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⑤④ Process and kit for sodium sulfite neutralization of H₂O₂ in contact lenses.

⑤⑦ Residual H₂O₂ remaining on a contact lens that has been disinfected in an H₂O₂ solution is neutralized by placing the lens in a buffered saline solution which contains an effective amount of sodium sulfite. Provided is also a kit including means for washing the lenses and a source for sodium sulfite.

PROCESS AND KIT FOR SODIUM SULFITE NEUTRALIZATION OF
H₂O₂ IN CONTACT LENSES

This application relates to the disinfection of contact lenses, and more particularly to disinfection by water-borne chemical agents without the application of heat.

Contact lenses accumulate dirt, proteinaceous matter, and microorganisms, all of which can adversely affect the health of the eye if allowed to accumulate on the lens. Therefore, the lenses must be cleaned and disinfected regularly and preferably daily.

It is generally known that hydrogen peroxide, in aqueous solution at a concentration of 3 wt. %, can be used to disinfect contact lenses and simultaneously remove unwanted dirt and proteinaceous matter. However, the hydrogen peroxide (hereafter, H₂O₂) will irritate the eye if even a small residual amount remains on the lens when it is re-inserted into the eye. This problem is especially notable with soft contact lenses, which are made from a water-permeable polymer into which the H₂O₂ can penetrate. Removing the H₂O₂ from such material is particularly difficult, and has required extensive washing and soaking with saline solution. Thus, it is desirable to be able to employ H₂O₂ in disinfecting contact lenses, while avoiding the irritancy of residual H₂O₂.

U.S. Patent No. 3,829,329 discloses immersing soft contact lenses in a normal saline (NaCl) aqueous solution of 3% H₂O₂, to shrink the lenses. The lenses were then boiled for 2 hours each in distilled water and normal saline solution. Adopting such a severe boiling regimen for the daily treatment of soft contact lenses would be inconvenient to the user and could cause the lenses to deteriorate.

1 U.S. Patent No. 3,908,680 discloses a treatment
regimen for plastic articles such as contact lenses, which
employs two boiling, aqueous baths containing a peroxy
compound such as H_2O_2 , followed by cleansing with a nonionic
5 detergent and rinsing with distilled water. This sequence,
besides being overly cumbersome for daily application, is
not sure to remove all residual H_2O_2 .

U.S. Patent No. 3,912,451 discloses that H_2O_2 in
a solution used to sterilize soft contact lenses can be
10 subsequently neutralized by contacting the solution with
a metallic catalyst which decomposes the H_2O_2 . This
system is not sure to work quickly, as it relies on diffu-
sion of the H_2O_2 to a solid metallic surface. Such a
system also becomes less and less effective as the concen-
15 tration of H_2O_2 declines; unfortunately, the H_2O_2 concentra-
tion at which this system loses efficiency can still be
high enough to risk irritation to the eye of the user. In
addition, this system requires several manual or mechanical
steps to bring the metallic catalyst into contact with the
20 H_2O_2 solution. One such mechanical approach is disclosed
in U.S. Patent No. 4,013,410, in which a mechanical timer
rotates the container holding the solution so as to bring
the solution into contact with a band of catalytic metal.

An article by A. R. Gasset et al., "Hydrogen
25 Peroxide Sterilization of Hydrophilic Contact Lenses", in
Arch. Ophthalmol, Vol. 93 (June, 1975) pp. 412-415, dis-
cusses sterilizing soft contact lenses in 3% H_2O_2 solution.
A solution of sodium thiosulfate was used to neutralize the
residual H_2O_2 remaining in the lenses after sterilization.
30 The authors found that sodium thiosulfate concentrations of
1.5% and 2.0% were unable to destroy all residual H_2O_2 ,
while a 2.5% solution was effective. However, sodium thio-

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1 sulfate needs a rather lengthy reaction time to ensure that
all the peroxide is neutralized.

The present invention provides a convenient, safe,
quick process for neutralizing residual H_2O_2 from a contact
5 lens which has been in contact with an aqueous solution of
 H_2O_2 , comprising:

(A) immersing the lens in an aqueous solution
which contains dissolved therein

(1) agents for buffering the pH of the solu-
10 tion to 6.5 - 8.5;

(2) one or more salts effective, with said
buffering agents, to provide the solution; under a tonicity
of 0.7 to 1.4%;

(3) an optional preservative; and

15 (4) sodium sulfite, in an amount at least
stoichiometric with respect to the residual H_2O_2 ; and

(B) keeping the lens immersed in said solution for
a sufficient period of time for the sodium sulfite to
neutralize the H_2O_2 completely.

20 In the preferred embodiment, the lens is immersed
in buffered isotonic saline solution, and a few drops of
an aqueous solution of sodium sulfite and a stabilizing
agent for the sodium sulfite are added to neutralize the
 H_2O_2 .

25 Another embodiment of this invention comprises a
kit including apparatus for holding and agitating the
lenses immersed in treatment solutions, plus a premixed
solution or tablet by which an effective amount of sodium
sulfite can be added to the treatment solution to neutral-
30 ize residual H_2O_2 .

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1 As indicated, the present invention effectively
and quickly neutralizes residual H_2O_2 from a hard or soft
contact lens. This invention is directed at H_2O_2 which
is on the lens surface and H_2O_2 which is within the lens,
5 i.e. which has penetrated into the matrix of a polymeric
hydrophilic ("soft") contact lens. Hydrophilic lens
materials are well known to practitioners in this field;
one example is polyhydroxyethylmethacrylate. Residual
amounts of H_2O_2 will generally comprise a total of less
10 than about 200 ppm of H_2O_2 , which can nonetheless irritate
the eyes.

The invention is most advantageously carried out
as part of a comprehensive regimen for cleaning the contact
lens. The regimen is preferably practiced with the aid
15 of a device of the type disclosed and claimed in U.S.
Patent No. 3,623,492, the disclosure of which is hereby
incorporated herein by reference. One such device, known
as a "Hydra-Mat II", includes two perforated baskets for
holding a pair of lenses inside a container which can hold
20 enough of a liquid treatment solution to immerse the lenses.
The baskets are connected by a rod to gears inside the lid
which closes the container. Twisting the lid rotates the
baskets about the axis of the rod, thereby washing the
lenses with the treatment solution.

25 The lens to be disinfected is first removed from
the eye and then cleaned, preferably by gentle rubbing
between the fingers with a commercial lens cleaning solu-
tion for 15 - 20 seconds, or by other appropriate methods
for cleaning. This step, while not an essential part of
30 the invention, helps loosen soil from the lens surface.
The loosened soil and the cleaning solution are then rinsed
off of the lens with a stream of commercial buffered

- 1 isotonic saline rinsing solution. Alternatively, the
dirt and cleaner are washed off by placing the lens into
a basket of the Hydra-Mat II, adding enough of the
rinsing solution (7 ml) into the container of the Hydra-Mat
5 II to immerse the lens, closing the lid over the container,
and then turning the lid to wash the lens through the solu-
tion.

The lens is next immersed in an aqueous solution
of H_2O_2 to disinfect the lens. Immersion is preferably
10 carried out in the Hydra-Mat II (after the rinsing solu-
tion has been discarded). Enough of the H_2O_2 solution is
placed in the container to immerse the lens in the basket,
and the lid is closed and turned to rotate the lens within
the solution. A 3 wt. % solution of H_2O_2 is acceptable,
15 in which case the lens should remain immersed in the solu-
tion for 5 to 10 minutes. H_2O_2 concentrations up to about
6 wt. % and as low as 0.25 wt. % are acceptable, provided
that the time period for which the lens is immersed in the
solution is longer for weaker solutions. A satisfactory
20 disinfecting period for any given concentration on H_2O_2
can be determined by observing the degree of disinfection
of a sample contaminated lens which is exposed to 3 wt. %
 H_2O_2 for 10 minutes, and observing how much time is needed
to achieve the same disinfection in another, equally con-
25 taminated lens in solution having an H_2O_2 concentration
other than 3 wt. %. For instance, the lens should be held
for about 6 hours in a 0.25 wt. % H_2O_2 solution, for about
3 hours in a 0.5 wt. % H_2O_2 solution, or for about 2 hours
in a 1 wt. % H_2O_2 solution.

30 Following disinfection of the lens in the H_2O_2
solution, the lens is removed from the H_2O_2 solution. The
 H_2O_2 solution is discarded. The lens is then immersed in
a buffered isotonic saline storage solution. These steps
can be performed by literally picking up the lens from
35 the solution and placing it into the next solution. In

1 the Hydra-Mat II the lens can be removed from the H_2O_2
solution without having to touch the lens; the lid is
removed with the lens still in its basket, and the con-
tainer is emptied and refilled with the storage solution.

5 The storage solution can be one of several rinsing
solutions currently available commercially, such as the
one sold under the same "Soft Mate" by Barnes-Hind/Hydro-
curve. The solution is buffered to a pH of 6.5 to 8.5,
and preferably 7.0 to 7.4, with a buffering system such
10 as a mixture of sodium borate and boric acid, or a sodium
phosphate or sodium bicarbonate buffer. The solution should
also have a sufficient tonicity to be essentially isotonic
with the fluids of the eye, i.e. having a tonicity of 0.7
to 1.4% NaCl equivalents. Those familiar with this art
15 will recognize that this range corresponds to 200 to 400
milliosmol (mOs) per kg of solution. To this end it can
contain 0.3 to 1.4 wt. % of sodium chloride and/or other
physiologically acceptable salts known in the ophthalmic
field such as chlorides of potassium, magnesium, or calcium.
20 The solution may also include an effective amount of a pre-
servative such as thimerosal, potassium sorbate, sorbic
acid, chlorhexidine, methyl or propyl paraben, chlorbutanol,
benzalkonium chloride, or phenyl mercuric acetate or nitrate.
The most preferred buffered system is boric acid/sodium
25 borate, which advantageously combines the functions of
buffering and aiding preservation.

The rinsing solution described in the preceding
paragraph has at best a slow neutralizing effect on H_2O_2
absorbed in or on the lens. Accordingly, the present
30 invention includes the step of adding to the solution an
amount of sodium sulfite (Na_2SO_3) effective to neutralize
the residual H_2O_2 . The amount added must be at least

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- 1 stoichiometric with respect to the total amount of H_2O_2
that is absorbed in or on the lens, at the time that the
lens is placed into the saline rinsing solution. Amounts
up to about 10 - 100 times stoichiometric or up to about
5 1000 ppm of sodium sulfite per lens are acceptable.

In the preferred embodiment, the sodium sulfite
is added as 3 to 5 drops of an aqueous neutralizing
solution containing 0.1 to 15 wt. % of sodium sulfite.
Preferably, the sodium sulfite concentration is 0.5 - 5
10 wt. %, and more preferably it is 2 - 3 wt. %.

A solution of sodium sulfite would be expected to
be chemically unstable, and therefore impractical as a
neutralizing agent. The solution would need a shelf life
of months (if not years) as the bottles in which it would
15 be sold to the public passed from the manufacturer, to
store shelves, to the home of the consumer, where the solu-
tion would be opened to atmospheric oxygen repeatedly during
use. Thus, in a noteworthy aspect of the present invention,
the neutralizing solution also contains dissolved therein
20 a stabilizing agent effective to prevent premature oxidation
of the sodium sulfite before the neutralizing solution is
added to the lens solution, and which is not injurious to
the lens or to the eye. The disodium salt EDTA is a pre-
ferred stabilizing agent; other satisfactory agents include
25 glucose, sodium lauryl sulfate, and propyl gallate. The
agent can comprise about 0.005 - 0.20 wt. % of the neutral-
izing solution, preferably about 0.01 - 0.10 wt. %, or up
to about 10% by weight of the sodium sulfite.

Sodium sulfite solutions so stabilized have been
30 found to retain over half their peroxide-neutralizing
activity when air was bubbled through the solution for 144
consecutive hours; this test presents relatively severe

1 conditions. In another test which simulated actual use
of the stabilized solution, a vial of the solution was
opened daily and 3-5 drops were removed with a dropper.
After a month, the peroxide-neutralizing activity was
5 still about 90%.

The solution of sodium sulfite also advantageously
contains a preservative to prevent growth of microorganisms
which could be introduced during repeated opening of the
solution container. The most preferred preservative is
10 a sodium borate/boric acid buffer that is effective to
control the pH of the solution to about 9, such as about
1 wt. % of this buffer. This system is effective to meet
the Antimicrobial Preservative Effectiveness Test (USP No 20).

In an alternate embodiment, the sodium sulfite
15 is added as a tablet (or several tablets) supplying suffi-
cient sodium sulfite to neutralize the residual H_2O_2 . The
tablet can contain 0.1 - 99 wt % sodium sulfite, plus inert
binders used in making the tablet according to conventional
techniques.

20 After the sodium sulfite is added to the storage
solution, the lens is preferably agitated within the solu-
tion, such as by turning the top of the Hydra-Mat II to spin
the lens through the solution. Neutralization is generally
complete in about 5 - 10 minutes. The rapidity of the
25 neutralization is an unexpected and advantageous feature
of the invention, especially compared to neutralization
with like amounts of other neutralizing agents. The
rapidity is especially advantageous to wearers of extended-
wear contact lenses, who frequently do not have a pair of
30 spectacles to use while they wait for their lenses to be
cleaned and neutralized.

1 The neutralization reaction converts the H_2O_2 to
water, and the sodium sulfite is converted to sodium
sulfate in solution which is inert to the lens. The lens
can be reinserted into the eye immediately, stored in the
5 resulting solution for several hours or overnight, or it
can be removed and immersed in fresh storage solution.

 Another embodiment of this invention comprises a
kit for disinfecting lenses with H_2O_2 and for neutralizing
the residual H_2O_2 on the lenses. The kit comprises a means
10 for washing the lens, and a source of sodium sulfite. The
kit can optionally include either or both of an aqueous
solution of H_2O_2 , and an aqueous, buffered, isotonic saline
solution.

 The lens washer means is advantageously of the type
15 having

 a container open at its top for receiving lens
washing fluid and a lens case agitator;

 a lidlike member removable mounted on the top end
of the container and open at both ends and having a trans-
20 verse partition intermediate its ends; said partition having
an aperture extending therethrough;

 a lens case agitator pivotally mounted in said
aperture in the partition and extending into said container
and having depending lens case supporting means and an
25 upper end extending above the partition and having a spur
gear thereon;

 a knoblike member pivotally received in the upper
end of the lidlike member and having finger grasp means for
rotating the same and internal gear teeth therein;

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1 planetary gear means pivotally mounted on said trans-
verse top portion of the lidlike member and interposed
between said spur gear on the agitator and said internal
gear teeth in the knoblike member for imparting rotation
5 to said agitator member whereby a lens carried in said
lens case is washed in the liquid in the container; or
the equivalent thereof.

The sodium sulfite source preferably comprises
a vial of an aqueous solution of 2 to 3 wt. % (preferably
10 2.5 wt. %) sodium sulfite, 0.5 to 3.0 wt. % (preferably
1 wt. %) sodium borate, and 0.005 to 3.0 wt. % (preferably
1 wt. %) disodium EDTA salt.

The saline solution can be a commercial buffered
saline rinsing solution. The solution should have a pH
15 of 7.0 to 7.4, and buffering agents such as sodium
borate/boric acid to maintain the pH in that range. The
solution also contains e.g. sodium chloride, to provide
a tonicity of 0.7 to 1.4 %, plus small but effective
amounts of a stabilizing agent, preferably disodium EDTA,
20 and of a preservative.

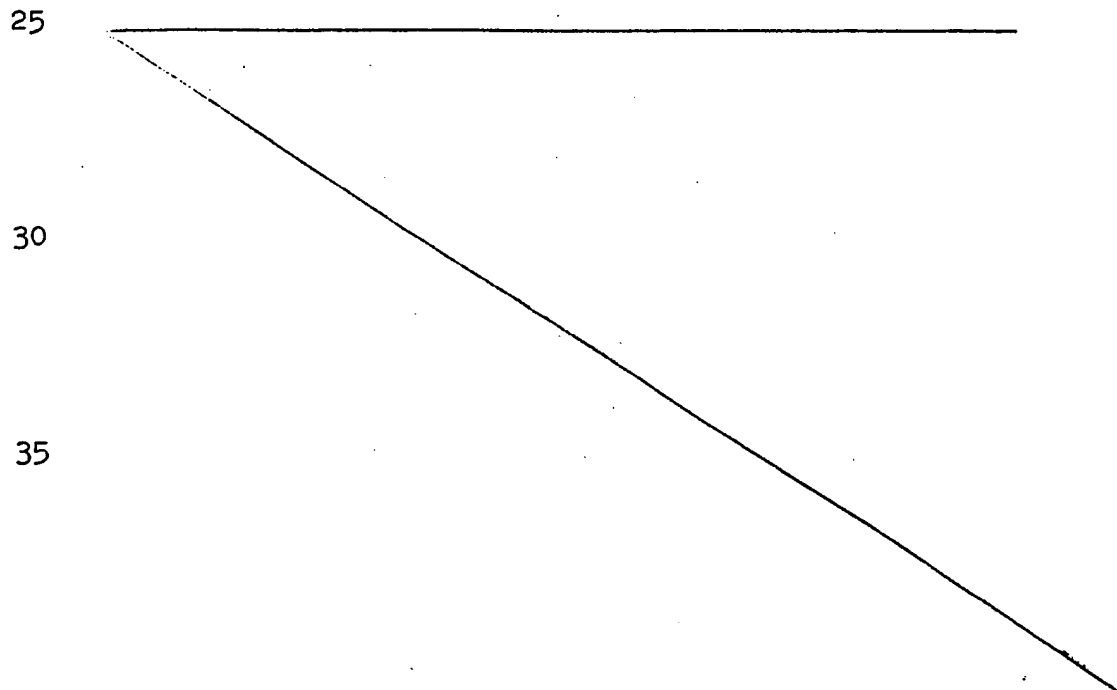
The H_2O_2 solution has a concentration of 1 to 6
wt. % and preferably about 3 wt. %. The H_2O_2 solutions
used herein advantageously include up to 0.05 wt. % of a
stabilizer which does not react with or discolor the lens.
25 A satisfactory stabilizer is a mixture of sodium stannate
and sodium pyrophosphate, in a ratio of about 60:40 to
40:60 by weight.

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1 The user removes the lens from the eye, carries
out the rubbing and rinsing steps described above, and
encloses the lens in the perforated holding basket of
the washing device. The user then places about 7 ml
5 of 3 wt. % H_2O_2 aqueous solution into the container of
the washing device, and closes the lid so that the lens
stays immersed in the H_2O_2 for about 5 to 10 minutes.
The kit ought to include instructions informing the user
how much of a given concentration of H_2O_2 solution to use,
10 and how long to keep the lens in the solution. Of course,
times other than 5-10 minutes are used with concentrations
other than 3 wt. %. A mark or line can be provided on
the side of the container to indicate the level that 7 ml
of solution reaches. Next, the user removes the H_2O_2
15 solution and replaces it with the saline solution buffered
to pH 7.0 - 7.4. Into this solution the user adds 3 to 5
drops of the sodium sulfite solution; the top of the device
can be twisted to help disperse the sodium sulfite in the
solution. The lens is stored in this solution for 5 to
20 about 10 minutes. At the end of this time, the total H_2O_2
content of the lens and the ambient solution is less than
40 ppm, and more advantageously less than 10 ppm. The lens
at this point can be worn without irritation to the eye.

The invention is described in the following Example:



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EXAMPLE 1

- One Hydrocurve II (55% water-bufilecon A 45%) lens was put in each of the two baskets of the Hydra-Mat II.
- 5 The container was filled with 7.0 ml of 3 wt. % of H_2O_2 . The lenses were immersed in the 3 wt. % H_2O_2 solution and the lid was turned for 15-20 seconds to agitate the lenses in the solution. After 10 minutes, the baskets were removed from the 3 wt. % H_2O_2 solution which was discarded.
- 10 The container and the lid with the baskets were rinsed thoroughly with a saline solution containing 0.75 wt. % sodium chloride, 0.01 wt. % disodium salt of EDTA, 0.368 wt. % potassium sorbate, 0.1% boric acid, with a pH of 7.0 and tonicity of 0.9 (sodium chloride equivalent). The.
- 15 container was filled with 7.0 ml of the saline solution mentioned above and 4 drops of a neutralizing solution containing 2.5 wt. % sodium sulfite, 0.01% disodium salt of EDTA and 1.0% borate with a pH of 9.2 were added. The lenses were immersed in the combined saline-neutralizing
- 20 solution and the baskets were agitated for 15-20 seconds. After 5 minutes, the total amount of the residual H_2O_2 in the solution and lenses was found to be less than 20 mg (less than 3 ppm at 7.0 ml).

It will be recognized that all components of the

25 solutions used herein should be non-irritating to the eye (except for the H_2O_2 itself, of course) and should be inert to the lens. Standard tests for determining non-irritability to the eye, and inertness to the lens, are known to those skilled in this field.

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CLAIMS

1. A process for neutralizing H_2O_2 absorbed in a hard or soft contact lens, comprising

5 (a) immersing the lens in an aqueous solution which container dissolved therein

(1) on or more buffering agents to buffer the pH of the solution to a value of 6.5 to 8.5;

10 (2) one or more salts effective with said buffering agents to provide the solution with a tonicity of 0.7 to 1.4%; and

(3) sodium sulfite, in an amount at least stoichiometric with respect to the amount of H_2O_2 to be neutralized; and

15 (b) keeping the lens immersed in said solution for at least enough time to permit the sodium sulfite to neutralize all the H_2O_2 .

20 2. The process of claim 1 wherein step (a) comprises initially immersing the lens in a storage solution containing components (1) and (2), and then adding to said storage solution a neutralizing composition containing component (3).

25 3. The process of claim 2 wherein said neutralizing composition comprises an aqueous neutralizing solution having a sodium sulfite concentration of 0.1 to 15 wt. % and containing a stabilizing agent in an amount up to about 10% by weight of said sodium sulfite.

30 4. The process of claim 3 wherein the stabilizing agent is the disodium salt of EDTA, glucose, sodium lauryl sulfate, or propyl gallate.

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1 5. The process of any of claims 2 to 4 wherein
the sodium sulfite concentration in said neutralizing
solution is about 2 to 3 wt. %.

5 6. The process of any of claims 2 to 5 wherein
the neutralizing composition comprises a water-soluble
tablet of sodium sulfite.

7. The process of any of claims 2 to 6 wherein
10 said storage solution also contains up to 1.0 wt. % of
a preservative.

8. The process of any of claims 1 to 7 wherein
the buffering agent is a mixture of boric acid and sodium
15 borate.

9. The process of any of claims 1 to 8 wherein
said one or more salts is sodium chloride.

20 10. A process according to any of claims 2 to 9
wherein the lens is immersed in the combined storage and
neutralizing solutions until the H_2O_2 content of the lens
and the combined solutions is less than 40 ppm.

25 11. The process of claim 10 wherein the pH of the
storage solution prior to addition of the neutralizing
solution is 7.0 to 7.4; the neutralizing solution contains
0.5 to 5 wt. % sodium sulfite; and the stabilizing agent is
the disodium salt of EDTA.

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1 12. A process for disinfecting a hard or soft
contact lens, comprising
 (i) immersing the lens in an aqueous solution
of 0.25 to 6.0 wt. % H_2O_2 for a period of time effective to
5 disinfect the lens;
 (ii) then removing the lens from the H_2O_2
solution; and
 (iii) neutralizing residual H_2O_2 in the lens
by carrying out the steps of any of claims 1 to 11.

10 13. A kit for neutralizing residual H_2O_2 absorbed
to contact lens, including means for washing the lens, and
a source of sodium sulfite, wherein the source is (1) an
aqueous solution containing 0.5 to 5 wt. % sodium sulfite
15 and a stabilizing agent in an amount up to 10% by weight of
the sodium sulfite, or (2) a tablet of sodium sulfite.

 14. A kit according to claim 13 wherein said means
for washing the lens comprises a container open at its top
20 for receiving lens washing fluid and a lens case agitator;
 a lidlike member removably mounted on the top
end of the container and open at both ends and having a
transverse partition intermediate its ends;

 said partition having an aperture extending
25 therethrough;

 a lens case agitator pivotally mounted in
said aperture in the partition and extending into said
container and having depending lens case supporting means
and an upper end extending above the partition and having
30 a spur gear thereon;

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1 a knoblike member pivotally received in the
upper end of the lidlike member and having finger grasp
means for rotating the same and internal gear teeth
therein;

5 planetary gear means pivotally mounted on
said transverse top portion of the lidlike member and
interposed between said spur gear on the agitator and
said internal gear teeth in the knoblike member for
imparting rotation to said agitator member whereby a
10 lens carried in said lens case is washed in the liquid
in the container.

15 15. A kit according to claim 13 or 14 further
comprising an aqueous, physiologically acceptable saline,
buffered solution having a pH of 7.0 to 7.4 and a tonicity
of 200 to 400 milliosmol/kg.

20 16. A kit according to claim 13 or 14 wherein the
washing means is an aqueous solution containing 0.25 to 6
wt. % H_2O_2 .

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European Patent
Office

EUROPEAN SEARCH REPORT

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Application number

EP 84 11 0127

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
Y	FR-A-2 269 968 (INTERNATIONAL OPTICAL CORP.) * Page 1, lines 14-18, 27-36; page 2, lines 1-12; claims 1-5 *	1-16	A 61 L 2/18 A 01 N 59/00 G 02 C 13/00
D, Y	FR-A-2 247 327 (FLOW PHARMACEUTICALS) * Claim 3; pages 11-13 *	1-12, 15, 16	
D, Y	US-A-3 623 492 (D.G. FRANTZ) * Claim 1 *	13-14	
A	GB-A-1 601 430 (CONTACT LENSES MANUFACTURING) * Claim 3 *	1	
A	FR-A-2 424 311 (SENJU PHARMACEUTICAL) * Claim 1 *	1	TECHNICAL FIELDS SEARCHED (Int. Cl. 4) A 61 L G 02 C
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 28-11-1984	Examiner PELTRE CHR.
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			